REMARKS

The Office Action dated May 6, 2004, has been received and reviewed.

Claims 1-22 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-22 stand rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter which is purportedly indefinite.

The recitation "to strengthen an immune system" in claim 22 has been objected to. Claim 22 has been amended to recite that that act of "administering" comprises administering a composition that includes a sufficient quantity of transfer factor to enhance an ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response to at least one antigenic agent, relative to the treated animal's normal T-cell mediate immune response to the at least one antigenic agent. It is respectfully submitted that one of ordinary skill in the art would readily understand the meaning and scope of claim 22, as amended.

With respect to claims 1-10 and 13-22, the Office asserts that the recitation "method for treating an animal," without indicating what is actually being treated, is indefinite.

Independent claim 1 has been amended to replace the recitation "method for treating an animal with transfer factor to elicit a T-cell mediated immune response" with "method for causing a treated animal to elicit a T-cell mediated immune response." It is respectfully submitted that, as amended, independent claim 1 recites the purpose of the acts included therein in a more definite fashion and in a manner that complies with the requirements of the second paragraph of 35 U.S.C. § 112.

Claims 2-10, 13-19, and 22 appear to have been rejected merely for depending from claim 1.

Independent claim 20 does not include the language that has been objected to. Instead, independent claim 20 recites a "method for causing an animal to elicit a T-cell mediated immune

response." It is respectfully submitted that the affects of the acts that are recited in independent claim 20 are clear from this recitation and, thus, that independent claim 20 is in condition for allowance under 35 U.S.C. § 112, second paragraph.

Claim 21 was apparently rejected for depending from claim 20.

Claims 11 and 12 have been rejected because the Office deems the phrase "disease state" to be unclear.

The phrase "disease state" is broader than the term "disease." It is understood by those of ordinary skill in the art that a "disease state" includes various conditions that precede and accompany a disease, as well as frank manifestation of the disease.

As a non-limiting example of a disease state, it is well known that *H. pylori* induces a strong inflammatory response at the site of infection and a localized area thereabout. Inflammatory cytokines are released from the localized area. As the inflammatory cytokines are transported through the circulatory system, they may cause irritation and inflammation of coronary arteries. For this reason, *H. pylori* is recognized as a major contributor to heart disease. Systemically circulating inflammatory cytokines may also cause strokes and Alzheimer's disease. The disease states in this example include the H. pylori infection and systemically circulating inflammatory cytokines that precede heart disease, stroke, or Alzheimer's disease, as well as each disease.

As another nonlimiting example, it is well known that non-traumatic inflammation or tissue injuries may result from infection, allergic responses, autoimmune conditions, or disease (*e.g.,* cancer). These are also recognized in the art as "disease states."

In view of the foregoing, it is respectfully submitted that claim 11 complies with the definiteness requirement of 35 U.S.C. § 112, second paragraph, and requested that the rejection of claim 11 be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 7-13, and 15-22 have been rejected under 35 U.S.C. § 102(b) for reciting subject matter which is purportedly anticipated by the subject matter disclosed in U.S. Patent 5,367,054 to Lee (hereinafter "Lee").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Lee describes methods for purifying IgY from eggs. The processes that are described in Lee are useful for obtaining IgY of 90% or greater purity. Lee describes a variety of different processes that may be used in purifying IgY from eggs, setting forth useful combinations of these processes in Fig. 1. Lee teaches that the purified IgY may be used for pharmaceutical purposes or as a health food ingredient. Col. 3, lines 38-40.

Initially, egg yolks are separated from whites, diluted, homogenized, further diluted in a salt-containing buffer, further homogenized, then phase-separated. Col. 5, lines 38-64.

As indicated in Fig. 1 of Lee, phase separation includes separation of an aqueous phase, from which IgY is purified, from a lipid phase, which Lee refers to as a "precipitate phase," from which "phospholipids and other important functional and biologically active components" may be obtained. Fig. 1; col. 5, lines 31-61. As transfer factor is inherently water-soluble, it would initially be present in the aqueous phase, which is subject to further processing to provide a product which is suitable for administration to an animal.

Notably, each of the purification paths shown in Fig. 1 of Lee includes at least one process that would result in the removal of transfer factor. For example, Lee discloses an ultrafiltration step, a gel filtration step, and a desalting step.

In the ultrafiltration step, larger molecules, such as antibodies, are separated from smaller molecules, such as transfer factor. Specifically, Lee discloses that ultracentrifugation of an aqueous, antibody-containing solution may be effected with a filter having a molecular weight cutoff (MWCO) of either 30,000 Da or 100,000 Da. Col. 5, line 65, to col. 6, line 14. As the

MWCO of the ultracentrifugation filter disclosed in Lee is much larger than the molecular weights of transfer factor molecules of the compositions that are administered in accordance with the claims of the above-referenced application, which the Office has deftly pointed out "is an inherent property of transfer factor" (Office Action of May 6, 2004, page 4) and is known to be less than about 10,000 Da, any transfer factor that may have otherwise been present in the purified aqueous, antibody-containing solution would be separated from the larger antibody molecules, which have molecular weights of about 168,000 Da. As a result, the resulting composition, which Lee indicates may subsequently be administered to a mammal, would not include transfer factor.

Lee also describes that ion exchange chromatograpy, including anion exchange chromatography or cation exchange chromatography, may be used to purify IgY. Col. 6, line 15, to col. 7, line 2. In ion exchange chromatography, the solid phase of the column somewhat selectively binds side chains of the molecule of interest, in this case molecules that are to be removed from the final product. As is well known in the art and suggested in Lee, the binding selectivity of the column must be specifically tailored to capture the molecule(s) of interest. Transfer factor is a hydrophilic, polar molecule. *See* U.S. Patent 5,840,700 to Kirkpatrick et al., col. 2, lines 39-41. Therefore, the highly polar solid phase materials of the types described in Lee would, more likely than not, capture transfer factor molecules, while IgY readily passes through such a column. *See,* Lee, col. 6, lines 47-55. Therefore, transfer factor would not necessarily remain in Lee's product following purification with an ion exchange column.

At col. 7, lines 3-15, Lee describes use of precipitation processes in the purification of IgY. The precipitation methods that are described in Lee, which are similar to those described in the above-referenced application, result in the precipitation of IgY from solution, while much smaller proteins, such as transfer factor, remain in solution, which is to be discarded.

Gel filtration, another process that Lee describes may be useful in purifying IgY (col. 7, lines 16-24), is also effected on the basis of molecular weight. Lee discloses that the compositions thereof need only include three components: γ-livetin (IgY), α-livetin, and β-livetin. As transfer factor molecules have smaller molecular weights than any of these desired molecules, they would remain trapped in the pores of the gel beads of a gel filtration column

longer than any of the desired molecules and, thus, would probably not be present in the resulting composition.

In the desalting step (col. 7, lines 25-37; col. 12, lines 40-58), which is necessary due to the presence of salt (from initial separation) in the purified IgY will adversely affect antigen-binding, the aqueous, antibody-containing solution of Lee is dialyzed. The description of Lee is limited to use of a dialysis membrane that has a MWCO of 12,000 Da to 14,000 Da. As the MWCO of the dialysis membrane disclosed in Lee is much larger than the molecular weights of transfer factor molecules of the compositions that are administered in accordance with the claims of the above-referenced application, any transfer factor that may have otherwise been present in the aqueous, antibody-containing solution would pass through the pores of the dialysis membrane and, thus, be removed from the solution. Thus, when the resulting composition is administered to a mammal, it would not include transfer factor.

Independent claim 1, as amended and presented herein, is directed to a method for elicting a T-cell mediated immune response in a treated animal. The method of independent claim 1 includes, among other things, administering to the animal a composition that includes an extract of an egg obtained from a nonmammalian source animal. The extract comprises transfer factor, which is generated by way of a T-cell mediated immune response of the nonmammalian source animal to at least one antigenic agent. Further, the extract comprises a "sufficient quantity of transfer factor . . . to initiate [the] T-cell mediated immune response in the treated animal."

Independent claim 20 also recites a method for causing an animal to elicit a T-cell mediated immune response. The method of amended independent claim 20 includes "administering to the treated animal a quantity of a composition including an extract of an egg obtained from a nonmammalian source animal." The extract includes "a sufficient quantity of transfer factor . . . to initiate [a] T-cell mediated immune response in the treated animal." Additionally, the method of independent claim 20 includes "permitting the transfer factor and the animal's immune system to initiate the T-cell mediated immune response *in vivo*."

It is respectfully submitted that Lee does not anticipate each and every element of independent claim 1 or independent claim 20.

Specifically, Lee does not expressly or inherently describe administering to a treated animal a composition that includes an extract of an egg with a sufficient quantity of transfer factor to initiate a T-cell mediated immune response by the treated animal. Instead, the description of Lee is limited to processes for purifying IgY, and which would also result in the removal of transfer factor.

Even assuming, for the sake of argument, that transfer factor were present in the eggs that are mentioned in Lee and, further, that residual amounts of such transfer factor were present in any of the compositions that are described in Lee, the transfer factor certainly would not be present in a quantity that is sufficient to initiate a T-cell mediated immune response in a treated animal.

Further, it is respectfully submitted that Lee lacks any express or inherent description of administering any of the intermediate compositions described therein to an animal. Initially, raw egg yolk is separated from egg white. Lee does not expressly or inherently describe that raw egg yolk may be administered to a treated animal or that raw egg yolk is even suitable for administration to a treated animal. Lee also lacks any express or inherent description that the initial intermediate "composition" thereof, diluted egg yolk, may be administered to a treated animal or is even suitable for administration to the treated animal. Once additional buffer is added to the initial composition described in Lee, the salt content of every composition until the final desalting step would render it unacceptable for administration to or effective use with the treated animal. As noted above, any transfer factor that may have been present in the eggs could be removed by each of the subsequent processing steps described in Lee.

Therefore, Lee does not expressly or inherently describe, or anticipate, each and every element of amended independent claim 1 or independent claim 20, as would be required to maintain the 35 U.S.C. § 102(b) rejections of independent claims 1 and 20.

Claims 2-3, 7-13, 15-19, and 22 are each allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 21 is allowable, among other reasons, for depending from claim 20, which is allowable.

For these reasons, withdrawal of the 35 U.S.C. § 102(b) rejections of claims 1-3, 7-13, and 15-22 is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 4-6 and 14 stand rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lee in View of Taylor

Claims 4-6 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter which is allegedly unpatentable over the subject matter taught in Lee, in view of the teachings of U.S. Patent 5,001,225 to Taylor (hereinafter "Taylor").

Claims 4-6 are allowable, among other reasons, for depending from claim 1, which is allowable.

Further, neither Lee nor Taylor teaches or suggest that a composition including *transfer factor* may be administered orally, nasally, or parenterally to initiate a T-cell mediated immune response in a treated animal. Notably, the teachings of Taylor are limited to methods for administering vaccines, while the compositions of Lee would include purified IgY. Due to chemical differences between transfer factor and vaccines or antibodies, one of ordinary skill in the art could not be certain from the teachings of Lee and Taylor that transfer factor from an egg could be administered in the same way as vaccines or antibodies.

Further, as there is no transfer factor present in the administered compositions of either Lee or Taylor, and because antibodies cannot elicit a T-cell mediated immune response, none of the modes of administration recited in claims 4-6 would result in the elicitation of a T-cell mediated immune response, as recited in independent claim 1, from which each of claims 4-6 depends. Therefore, it is respectfully submitted that one of ordinary skill in the art would have no reason to expect that the asserted combination of teachings from Lee and Taylor would work. For the same reason, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine the teachings of Lee and Taylor in the manner that has been asserted.

Lee in View of Dekich

Claim 14 is rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is purportedly unpatentable over teachings from Lee, in view of the subject matter taught in Dekich, Broiler Industry Strategies for Control of Respiratory and Enteric Diseases, Poultry Science, 77:1176-80 (1998) (hereinafter "Deckich").

Claim 14 is allowable, among other reasons, for depending from claim 1, which is allowable.

In view of the foregoing, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 4-6 and 14 is respectfully requested.

CONCLUSION

It is respectfully submitted that each of claims 1-22 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

Brick G. Power
Registration No. 38,581
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: September 7, 2004

BGP/rmh

Document in ProLaw